Remarks/Arguments

Claims 90-96 and 113-114 are pending for the Examiner's review and reconsideration. Applicants present the following remarks to address the concerns expressed in the final Office Action dated December 15, 2006.

Claims 90 and 92 have been amended to replace the recitations "about 13 wt-% to about 30 wt-% superdisintegrant," "about 6 wt-% to about 12 wt-% tannic acid," and "about 60 wt-% to about 85 wt-% of a hydrogel" with "about 10 wt-% to about 75 wt-% superdisintegrant," "about 2 wt-% to about 12 wt-% tannic acid," and "about 20 wt-% to about 70 wt-% of a hydrogel," respectively. These amendments are supported on page 13, lines 21-28 of the application as filed. Claims 90 and 93 have been amended to present the claims in better form. These amendments are supported, for example, on page 22, lines 19-26 of the application as filed. Claim 92 has been amended to add the proviso that the first particles and the second particles are not released at the same time. This amendment is supported on page 19, lines 15-16 of the application as filed. New claims 113 and 114 have been added. These claims are supported by original claims 90 and 93. Accordingly, no new matter has been added to the claims.

Claims 90-96 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement for the reasons set forth on pages 2-3 of the Office Action. This rejection has been rendered moot by the amendment of the claims.

Claims 90-96 also stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. patent No. 6,322,819 ("'819 patent") in view of U.S. patent No. 4,326,525 ("'525 patent") for the reasons set forth on pages 3-5 of the Office Action. In particular, the Office asserts that the '819 patent discloses a multiple pulsed dose delivery system containing methylphenidate with an disintegration agent and a hydrogel and the '525 patent discloses a dosage form containing methylphenidate and tannic acid. According to the Office, the combination of the delivery system of the '819 patent with the tannic acid disclosed in the '525 patent results in the dosage form recited in the claims. Applicants respectfully traverse.

The claims recite a pharmaceutical dosage form for oral administration to a patient providing pulsed gastric release of methylphenidate comprising a gastric retention vehicle composition comprising about 10 wt-% to about 75 wt-% superdisintegrant, about 2 wt-% to about 12 wt-% tannic acid, and about 20 wt-% to about 70 wt-% of a hydrogel, wherein, upon

contact with gastric fluid the gastric retention vehicle composition expands to promote retention of the dosage form in the patient's stomach and wherein methylphenidate is released into the stomach in at least two portions.

The disclosure of the '819 patent differs from the recitations of the claims at least in that it does not describe a gastric retention vehicle that expands to promote retention of the dosage form in the patient's stomach in order to accomplish pulsed gastric release of a drug. The '819 patent discloses a pharmaceutical composition that releases a drug in a first portion in the stomach (immediate release) and a second portion in the small intestine (enteric release). '819 patent, col. 3, ll. 23-38. It does not disclose a gastric retention vehicle that expands to promote retention in the stomach so as to accomplish pulsed release of the drug in at least two portions in the stomach, as recited in the claims. In addition, the '819 patent does not disclose the use of tannic acid in a gastric retention vehicle, as recited in the claims.

The '525 patent cannot remedy the above-described deficiencies of the '819 patent because it likewise does not disclose or suggest a gastric retention vehicle having the release characteristics recited in the claims.

The '525 patent discloses a device that accomplishes controlled release, rather than pulsed release, of a drug. '525 patent, col. 2, ll. 40-54. Further, the '525 patent does not teach or suggest that it would be desirable, or even feasible, to accomplish pulsed release of a drug with the disclosed device. By its silence, the '525 patent would not motivate one of ordinary skill in the art to modify the composition of the '819 patent such that it would accomplish pulsed release of a drug in the stomach, as recited in the claims.

Further, the '525 patent discloses the use of tannic acid to increase the solubility of the beneficial agent by its interaction with the beneficial agent in the core of the disclosed device. *Id.* at col. 7, l. 21 to col. 8, l. 47. The claims, however, recite the use of tannic acid as part of the delivery vehicle itself, and not in the core along with the drug. Thus, one of ordinary skill in the art would have to both select tannic acid from among the multitude of buffers disclosed in the '525 patent and choose to remove the tannic acid from the core and place it in delivery vehicle, without any guidance. Because the '525 patent does not provide any guidance to make these modifications, the '525 patent's disclosure of the use of tannic acid in the core would not motivate one of ordinary skill in the art to modify the composition of the '819 patent to include tannic acid as part of the delivery vehicle, as recited in the claims.

For these reasons, the combined disclosures of the '819 patent and the '525 patent

would not motivate one of ordinary skill in the art to arrive at the dosage form recited in the claims. Accordingly, the rejection of claims 90-96 as obvious over the '819 patent in view of the '525 patent should be withdrawn.

In view of the foregoing amendments and remarks, Applicants respectfully submit that the present application is in condition for allowance. Early and favorable action by the Examiner is earnestly solicited. If any outstanding issues remain, the examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same. No fee is believed to be due for the submission of this response. Should any fees be required, please charge such fees to Kenyon & Kenyon, LLP Deposit Account No. 11-0600.

Respectfully Submitted,

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